K012683

NOV 0 8 2001

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter:	SterilMed, Inc.
Contact Person:	Patrick Fleischhacker 11400 73rd Avenue North Minneapolis, MN 55369 Ph: 763-488-3400 Fax: 763-488-3350
Date Prepared:	August 9, 2001
Trade Name:	Reprocessed Light Pipes
Classification Name and Number:	Endoilluminator Class II, 21 CFR 876.1500
Product Code:	MPA
Predicate Device(s):	The reprocessed light pipe is substantially equivalent to Endolight™ Fiberoptic Endoilluminator (K970875), manufactured by American Medical Devices; MicroLight™ Endoilluminator (K884043), manufactured by Grieshaber; and the counterpart devices from the original manufacturers. Please see Table 1 for additional predicate device information.
Device Description:	The light pipe is comprised of five basic components: the handpiece handle; the handpiece tube; the fiberoptic cable; the fiberoptic sheath; and the connector.
Intended Use:	The reprocessed light pipes are intended to be used to illuminate with visible spectrum light the intraocular portion of the eye for improved visualization during ophthalmic surgery.
Functional and Safety Testing:	Representative samples of reprocessed light pipes underwent bench testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.

Conclusion:	The reprocessed light pipe is substantially equivalent to: Endolight™ Fiberoptic Endoilluminator (K970875), manufactured by American Medical Devices MicroLight™ Endoilluminator (K884043), manufactured by Grieshaber and the counterpart devices from the original manufacturers.

Table 1
Comparison of Subject Devices' and Predicate Devices' Characteristics

Device Characteristics	SterilMed's Reprocessed Light Pipes	American Medical Devices' Endolight (K970875)	Grieshaber's Micro Lite (K884043)
Device Description	The light pipe is comprised of five basic components: the handpiece handle; the handpiece tube; the fiberoptic cable; the fiberoptic sheath; and the connector.	Same	Same
Intended Use	The reprocessed light pipes are intended to be used to illuminate with visible spectrum light the intraocular portion of the eye for improved visualization during ophthalmic surgery.	Same	Same
Principles of Operation	The fiber optic light pipe is connected to the light source and manually directed to illuminate the area within the eye where surgery is to be performed. The light pipe provides a more precise illumination for surgery.	Same	Same
Diameter	19 and 20 gage	19 and 20 gage	19 and 20 gage
Materials			
Handpiece	*Same	Delrin	Delrin
Handpiece Tube	*Same	Stainless Steel	Stainless Steel
Sheath	*Same	Unknown	PVC

Fiberoptic Cable	*Same	PMMA	PMMA
Connector	*Same	Aluminum	Aluminum
Sterility	EtO SAL^{-6}	Same	Same
Product Code	MPA	Same	HQE

*Same materials as American Medical light pipes, Grieshaber light pipes, or previously approved devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Patrick Fleischhacker
Vice President
Regulatory and Quality Control
SterilMed, Inc.
11400 73rd Avenue North
Maple Grove, MN 55369

Re: K012683
Trade/Device Name: Reprocessed Light Pipes
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: MPA
Dated: October 15, 2001
Received: October 30, 2001

Dear Mr. Fleischhacker:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Indications for use Page

Device Name: Reprocessed Light Pipes

Indications for Use:

The reprocessed light pipes are intended to be used to illuminate with visible spectrum light the intraocular portion of the eye for improved visualization during ophthalmic surgery.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012683